

REMARKS

The Office Action mailed May 6, 2003 has been received and carefully considered.

Upon entry of the preceding amendments, claims 1-42 will be pending. Claims 1-26 are withdrawn from consideration and claims 27-42 are currently under examination. Claims 27-31 stand rejected. All amendments, including the new claims, present no new matter and are supported at least at pages 6-7 and throughout the specification and claims as originally filed.

Reconsideration in light of the preceding amendments and remarks which follow is respectfully requested.

I. Communications with the Patent Office

Applicant thanks Examiner Venkat for the facsimile of a revised Restriction Requirement sent March 27, 2003 in response to an interview held March 26, 2003. In the interview, the Examiner indicated that claim 31 had erroneously been omitted from claim group IV, elected by Applicant. Following receipt of the fax, Applicant's representative contacted the Examiner to inquire whether a new time period for response was started, as Applicant had already timely replied to the original Restriction. Applicant thanks Examiner Venkat for the courtesy of a reply received on April 3, 2003 indicating that no new time period was set and that the revised Restriction was to correct the error and place claim 31 in group IV. Applicant also thanks Examiner Azpuru, who Applicant notes properly examined claim 31 along with the other claims of group IV in the current Office Action.

II. New Claims

Claims 32-42 have been added, all of which depend from claim 27.

III. Election/Restriction

In re U.S. Patent Application of Jens PETERSEN
Serial No.: 09/938,669 Filing Date: August 27, 2001
Title: POLYACRYLAMIDE HYDROGEL AS A SOFT TISSUE FILLER
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The Applicant notes that the Examiner has made final the restriction requirement of Paper No. 9. Applicant continues to traverse the requirement and reserves the right to file one or more divisional applications to the withdrawn claims and any other subject matter disclosed or claimed in the Application as filed. Applicant also reserves the right to later rejoin withdrawn claims in accordance with M.P.E.P. § 821.04.

IV. Rejection under 35 U.S.C. § 112

Claim 31 was rejected in the Office Action under 35 U.S.C. § 112, second paragraph as indefinite based on the use of the phrase “such as.” Applicant submits that claim 31 as amended overcomes this formal rejection. Withdrawal of this rejection is requested.

V. Double Patenting Rejection

Claims 27-31 provisionally stand rejected under the judicially created doctrine of obviousness-type double patenting. These claims are provisionally rejected over claims 18 and 19 of copending U.S. Application No. 09/938,667, claims 13-15 of copending U.S. Application No. 09/938,670, and claims 27-35 of copending Application No. 09/938,668.

The Patent Office has not yet indicated that any of the claims in this or the copending applications contain patentable subject matter. Accordingly, Applicant respectfully requests that the provisional double-patenting rejection be held in abeyance until such time as any of the identified claims have been indicated as allowable.

VI. Rejection under 35 U.S.C. § 103(a)

Claims 27-30 are rejected under 35 U.S.C. § 103(a) as unpatentable over EP 0 727 232 to Brunstedt et al. (“Brunstedt”). The Applicant respectfully traverses this rejection.

As stated by the Federal Circuit, “a proper analysis under 35 U.S.C. § 103 requires, *inter alia*, consideration of two factors: (1) whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition or device, or carry out the claimed process; and (2) whether the prior art would also have revealed that in so making or carrying out, those of ordinary skill would have a reasonable expectation of success.” *In re Vaeck*, 947 F.2d 488, 493 (Fed. Cir. 1991). In addition, the prior art reference(s) must teach or suggest all of the claim limitations. The teaching or suggestion to combine and the reasonable expectation of success must both be found in the prior art, and not in Applicant’s disclosure. *Id* at 493. *See also* M.P.E.P. § 2142.

Brunstedt does not teach, disclose or suggest a prosthetic device as claimed by Applicant in claim 27 or its dependent claims, 28-42. Brunstedt teaches a surgically implantable soft tissue implant filling material. Col. 3, lines 7-8. The filling material must be placed inside a compatible shell or membrane to prevent substantial leaking or bleeding of the filling material. Col. 4, lines 46-51.

Unlike Brunstedt, Applicant’s claimed invention is a prosthetic device which is injectable into soft tissue. Nowhere does Brunstedt teach, disclose or suggest that the filling material alone may be injected or otherwise placed in direct contact with the body. In fact, Brunstedt clearly teaches away from the claimed invention by teaching that the filling material must be placed in a compatible shell material to prevent substantial leakage or bleeding of the filling material. The shell is selected particularly for its compatibility in preventing the filling material from leaking into the body. Col. 4, lines 46-51. This suggests that Brunstedt’s filling material, as its name

implies, should not have direct contact with soft tissue, unlike the Applicant's claimed prosthetic device which is injectable into soft tissue.

Any filling material which may leak from the shell of Brunstedt's invention is apparently either excreted or metabolized. Col. 6, lines 1-2. Again, this clearly teaches away from the Applicant's claimed invention. While the claimed invention is injectable into soft tissue, any contact with the tissue by the filling material of Brunstedt is clearly accidental and is subsequently eliminated from the body by excretion or metabolism.

For similar reasons, a person ordinarily skilled in the art who develops a filling material to be contained within a shell would not have the same motivations as a person developing a prosthetic device which may be injected into soft tissue. A material which is injectable into soft tissue presents a host of considerations, including various desirable physical properties and biocompatibility aspects, which would not be considered by one developing a filling material that is contained within a shell and not in direct contact with tissue.

Thus, Brunstedt does not teach, disclose, or suggest every element of Applicant's claimed invention, nor would one skilled in the art be motivated to modify Brunstedt to arrive at the claimed invention. A modification of Brunstedt's disclosure involving separation of the filling material from the shell, and the use of the filling material alone (contrary to Brunstedt's explicit teaching) could only have been made with the benefit of hindsight provided by Applicant's own invention. The use of hindsight in patentability analysis is erroneous as a matter of law. *See In re Dance*, 48 U.S.P.Q.2d 1635 (Fed. Cir. 1998).

Because a *prima facie* case of obviousness has not been established, Applicant respectfully submits that this rejection should be withdrawn.

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Conclusion

For at least these reasons, claim 27 and claims 28-42, which depend from claim 27, have been demonstrated to be in condition for allowance. Accordingly, Applicant respectfully requests that the Application be allowed and passed to issue.

In the event any outstanding issues remain, Applicant would appreciate the courtesy of a telephone call to Applicant's undersigned representative to resolve such issues in an expeditious manner.

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Respectfully submitted,

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